EXHIBIT 77

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Case Report
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Forced Air Warming Device Failure Resulting in Smoke and Soot on a Surgical Patient

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Introduction

Forced air warming (FAW) devices are used in the operating room to helpmaintain normothermia during anesthesia and prevent complications of hypothermia. Proper use involves connecting the hose of the warming unit to a disposable blanket with a perforation pattern that evenly distributes heat across the patient's body. Multiple studies have shown the efficacy of FAW devices to be better than other widely used interventions such as circulating water mattresses [1]. However, as with most medical interventions there is a potential for complications with FAW devices. We present the case of a FAW device that malfunctioned after it became wet, depositing black soot on the patient.

Case Report

A 67 year old male patient with a history of hypertension, dyslipidemia, and lung cancer presented for a robotic-assisted left upper lobectomy. The patient was taken to the operating room where standard ASA monitors were applied. General anesthesia was induced, and the airway was secured with a 35 French left double lumen tube. A radial arterial line and addition IV lines were placed, after which the patient was positioned in the right lateral decubitus position. The patient's initial bladder temperature was 35.7°C. A FAW blanket was applied to the patient's lower body, and the heating device was set to 43°C. During the procedure, the patient's temperature decreased to 35.0°C and recovered to 35.8°C by the end of surgery. While closing the chest, the line isolation monitor alarm was heard and was investigated. A few minutes later smoke was noticed in the field, and the drapes were removed to identify the source. No flames were seen, and no obvious source of smoke was identified. Then, black punctate spots were noted on the sheets and the patient's lower extremities (Figure 1). Upon investigation, the black spots were soot deposited on the patient in the pattern of the perforation holes of the FAW blanket. The soot was wiped off the patient, and there was no injury to the patient. The blanket itself was dry, but the warming unit was sitting in irrigation thatspilled from the surgical field.

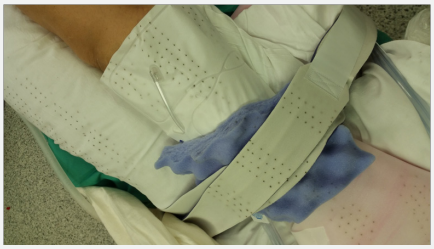

Figure 1: Black punctate spots were noted on the sheets and the patient's lower extremities.

Discussion

The Food and Drug Administration and Anesthesia Patient Safety Foundation discourage "hosing" [2-3], defined as the misuse of FAW devices by applying the hose directly to the patient or to a non-inflatable blanket. This misuse has resulted in various reports of first to third degree burns [4-6], including a reported amputation due to muscle necrosis. In our case, however, the FAW device was properly utilized with the hose attached to an inflatable blanket. Our institutional biomedical service evaluated this incident and device and concluded that the air-intake on the bottom of the unit entrained irrigation into the device, causing a short circuit within the unit. This electrical short created smoke inside the device, which was then blown out through the hose and deposited as soot through the perforation holes in the inflatable blanket. The unit was removed from service and returned to the manufacturer.

This is a near-miss case that could easily have resulted in a fire or electrical shock. The use of line isolation monitors is meant to decrease the risk of electrical shock in the operating room (OR). Common electrical circuits outside of the OR consist of a grounded system where an individual could be electrocuted by completing the electrical circuit. To provide additional safety in the OR, the isolated electrical system is ungrounded and requires two faults in order to cause electrocution [7]. When the

first fault occurs, the line isolation monitor will alarm. Electrical equipment should then be unplugged in reverse sequence until the alarm stops, which indicates the cause of the first fault. In this case, the FAW device was identified as the cause.

Documented complications from FAW use include an increased incidence of surgical site infections and some instances of burns due to misuse as mentioned above [4-6]. However, to our knowledge, electrical issues have not been reported. In order to prevent similar events and improve OR safety, we now attach our FAW devices to an elevated platform to ensure the device does not contact fluid on the floor.

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